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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,628	03/09/2001	William J. Curatolo	PC8626CMAS	7884

7590 03/26/2002

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EXAMINER
DEWITTY, ROBERT M

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/803,628	CURATOLO ET AL.	
	Examiner	Art Unit	
	Robert M DeWitty	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-71 and 149-214* is/are pending in the application.

4a) Of the above claim(s) *1-71,151-163,165-172, 176-207, 213, and 214* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *149,150,164,173-175 and 208-212* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-71 and 149-214* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-71 and 149-214 are pending in the instant application. Claims 1-71, 151-163, 165-172, 176-207, 213, and 214 are withdrawn as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 149 and 150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (U.S. Pat. No. 5,605,889).

Curatolo teaches a dosage form of azithromycin which can be administered to a mammal. The goal of Curatolo's dosage form is to address "food effect", i.e., the presence of food in the gastrointestinal tract adversely effecting the residence time of a therapeutic agent by not allowing sufficient absorption into the bloodstream. The dosage form can be in the form of a tablet, including both swallowable-only and chewable form (col. 2, lines 49-51). The azithromycin dosage forms as taught by Curatolo can provide azithromycin ready for dissolution in the gastrointestinal tract immediately following ingestion or they disintegrate rapidly following ingestion. It is believed that if the azithromycin dosage form provides azithromycin within a certain time

period following ingestion, the azithromycin will be absorbed into the bloodstream at a rate which results in substantially no food effect. At least about 90% of the azithromycin dissolves within about 30 minutes of ingestion (col. 5, lines 6-24). The tablets can include a variety of ingredients including disintegrants, binders, lubricants, etc. (see col. 6-col. 7).

It is understood by the examiner that the dosage form as taught by Curatolo is controlled (delivering an amount of azithromycin in a time period), and that, because dissolution occurs in the gastrointestinal tract, which can include the mouth and stomach, dissolution occurs distal to the duodenum.

3. Claims 149, 150, 164, 173-175, and 208-212 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (U.S. Pat. No. 5,605,889) further in view of Urquhart et al. (U.S. Pat. No. 4,434,153).

As stated above, Curatolo teaches a controlled dosage form that delivers azithromycin to the gastrointestinal tract. However, Curatolo does not teach a matrix for delivery of such dosage form.

Urquhart relates to a drug delivery system. Urquhart has as its object the delivery of a drug reservoir that releases drug in the stomach for absorption in the stomach. It is taught that if a delivery system is made available that remains in the stomach for releasing drug at a controlled rate for achieving therapeutic blood levels, such a delivery system would be clinically useful in the practice of medicine (col. 2, lines 9-25). The model is a drug delivery device housing a multiplicity of tiny pills for the

controlled delivery of drug over time. The tiny pills comprise a core of drug surrounded by a wall formed of rate-releasing controlling material (col. 3, lines 48-55). The delivery device can be made with a reservoir. The reservoir is formed from hydrogels that exhibit the ability to swell in water and retain such water in its structure. Suitable materials for the hydrogel include cellulose gum or gelatin (col. 4, lines 10-32). The wall surrounding the drug can be made of fatty ester mixed with a wax (col. 4, lines 46-50). Examples of suitable drugs that may be contained in the delivery device include erythromycin and the like (col. 6, lines 20-21).

Motivation to utilize the delivery design of Urquhart for the dosage form of Curatolo would have arisen because Urquhart's delivery design releases drug into the stomach of the gastrointestinal tract, thereby allowing absorption into the bloodstream. Such absorption would allow therapeutic blood levels to be reached, thus addressing the risks of "food effect".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD
March 21, 2002

JOSE' G. DEES
SUPERVISORY PATENT EXAMINER
1616